

Notice of Allowability	Application No.	Applicant(s)	
	09/993,669	KARLSSON ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to declaration (9/12/08), terminal disclaimer and IDS (1/27/09).
2. ☒ The allowed claim(s) is/are 65,66,68-144 and 148-153.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/230,781.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>1/27/09</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>2/17/09</u>. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
|---|--|

/Leigh C. Maier/
Primary Examiner, Art Unit 1623

DETAILED ACTION

Allowable Subject Matter

The declaration filed on September 12, 2008 under 37 CFR 1.132 is sufficient to overcome the references set forth in the previous Office action. The declaration establishes that the budesonide products for sale before the earliest priority of the instant application do not meet the limitations of the instant product.

Claims 65, 66, 68-144 and 148-153 are allowed for reasons of record.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Janis Fraser on February 17, 2009.

IN THE CLAIMS:

Cancel claims 146, 147 and 154-157.

Interview Summary

Obvious-type double patenting: The examiner noted that there had been no restriction made in the parent application, SN 09/230,781 (US 6,392,036). The claims in this patent are drawn to a particular process of the sterilization of a glucocorticosteroid, with budesonide being particularly recited. Carrying out this procedure as claimed would result in the instantly claimed product. The instant claims would be subject to obvious-type patenting.

Ms. Fraser agreed to submit a terminal disclaimer. This TD has been submitted and found acceptable to overcome this potential rejection.

Information disclosure statement: The examiner noted that an IDS letter discussing the various exhibits attached to Dr. Ekelund's declaration was filed September 12, 2008. However, there is no form PTO-1449 listing these references to be initialed. If these references are to be listed on the face of a patent issuing from this application, Applicant must submit such a form for initialing.

Ms. Fraser agreed to submit a form with the references listed. The initialed form is attached to this action.

Cancelled claims: In order to expedite allowance of claims, Ms. Fraser agreed to cancel the claims not reciting a purity limitation: 146, 147 and 154-157.

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Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday and Friday from 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

/Leigh C. Maier/
Primary Examiner, Art Unit 1623